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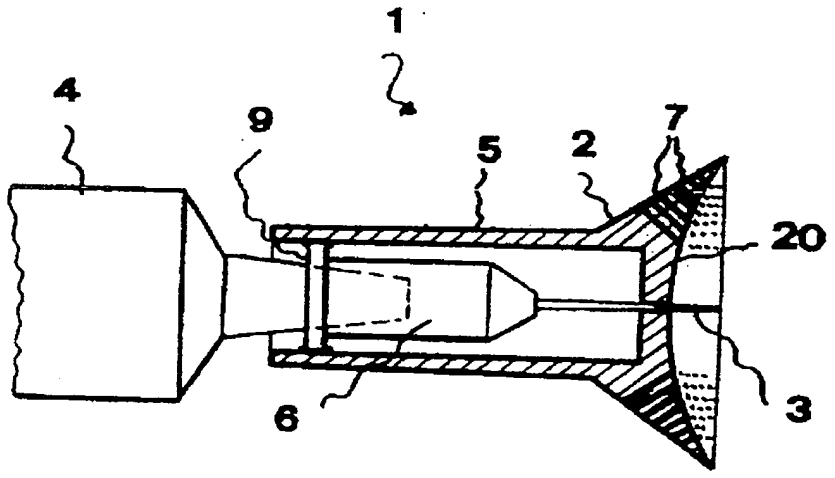
(54) Title: DEVICE FOR CONTROLLING THE PENETRATION DEPTH OF A NEEDLE, FOR APPLICATION TO AN INJECTION SYRINGE



(57) Abstract

The invention relates to a device for controlling or adjusting the penetration depth of a needle, specifically designed for application to an injection syringe, comprising an element designed for contacting a person's skin, said contact element including a surface which encompasses, at least partially, the tip of the needle. The contact element is operatively associated with syringe coupling means and comprises a plurality of throughgoing micro–holes passing through the surface.

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Description

DEVICE FOR CONTROLLING THE PENETRATION DEPTH OF A NEEDLE, FOR APPLICATION TO AN INJECTION SYRINGE

BACKGROUND OF THE INVENTION

The present invention relates to a device for controlling the penetration depth of a needle, for application to an injection syringe.

As is known, several substances are conventionally injected into the human body, for example intracutaneously, i.e. by injections which affect substantially only the surface layer of the human derma.

In particular, for performing the above mentioned injections, it is necessary to cause a syringe needle to enter for a limited length the patient derma.

On the other hand, as prior syringes are used for the above mentioned application, it is difficult to obtain a proper penetration depth of the needle, since this penetration depth substantially depends on the manual skillness of the operator.

In this connection, it should be apparent that an excessive penetration of the syringe needle would originate a disagreable pain feel for the patient, while preventing the injected substance from being properly absorbed.

A further aspect to be considered is that intradermal injection treatments, such as, in particular, those of a dermatological type, would require a comparatively high number of intradermal or

intracutaneous injections, thereby the above mentioned problems will recursively occur.

SUMMARY OF THE INVENTION

Accordingly, the aim of the present invention is to provide a device for controlling or adjusting the penetration depth of a syringe needle, which is specifically designed for application to an intradermal injection syringe, which allows the injections to be performed in an optimum manner.

The above aim is achieved by the present invention providing a device for controlling the penetration depth of a needle, for application to an injection syringe, characterized in that said device comprises a skin contacting element, said skin contacting element including a surface encompassing, at least partially, the tip of said needle, and in that said skin contacting element is operatively associated with coupling means for connection with said syringe.

According to a preferred embodiment of the present invention, the skin contacting element comprises an end tapering portion ending with the above mentioned surface.

Preferably, said surface has a spherical cap configuration and has its concavity facing the needle tip.

Moreover, the needle tip projects for a short length from said surface.

According to a further preferred embodiment of the present invention, the mentioned end tapering portion is provided with a plurality of throughgoing

holes passing through said surface.

According to a further preferred embodiment of the invention, the means for coupling the skin contacting element and syringe comprise an outer cylindric body ending with said tapering portion and an inner cylindric body, substantially coaxial to the outer cylindric body supporting the syringe needle.

Finally, the inner cylindric body comprises a circular rim or edge, opposite to the end portion the needle tip projects from, and the circular rim or edge is arranged inside the outer cylindric body.

The invention provides the following advantages, with respect to the prior art.

Firstly, the device according to the present invention allows to accurately adjust the needle penetration depth, without the need of performing manual controlling operations by the operator.

Secondly, the provision of throughgoing microholes or any other throughgoing holes, through the end tapering portion of the device, allows to prevent any suction effect due to the pressure difference between the inside of the tapering portion and the outer atmospheric pressure, thereby allowing air to outflow.

Thus, the syringe will be prevented from adhering to the skin of the patient by its end tapering portion, which would compel the operator to forcibly detach the syringe from the patient.

This suction cup effect would be particularly dangerous in all those cases in which the medical treatment provides a plurality of

subsequent injections.

Moreover, the use of a suitably contoured surface, to be slightly pressed against the skin of the patient, will allow to sensitize the region encompassing the needle puncture region, thereby the slight pain feeling affecting the patient during the intradermal injection will be further diluted or reduced, to assure, mainly in a case of a plurality of subsequent injections, a greater pain release for the patient.

Finally, the device according to the present invention can be easily constructed by using easily commercially available elements and materials and, moreover, said device can be used with existing syringes.

BRIEF DESCRIPTION OF THE DRAWINGS

Further advantages and characteristics of the present invention will become more apparent hereinafter from the following disclosure, given by way of an illustrative but not limitative example, with reference to the accompanying drawings, where:

Figure 1 is a partially cross-sectioned side view of the device for controlling the penetration depth of a needle according to the present invention, and of a syringe the device is associated with;

Figure 2 is a side view of the syringe assembly fitted to the device for controlling the needle penetration depth;

Figure 3 is a partially cross-sectioned view, on an enlarged scale, of the subject device for

controlling the penetration depth of a needle; and

Figure 4 is a further partially cross-sectioned view, on an enlarged scale, of the subject device for controlling a needle penetration depth, during the carrying out of an intradermal or intracutaneous injection.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

In the following disclosure reference will be made to a preferred embodiment of the invention, which will be illustrated as a not limitative example of several possible variations of the invention.

Figure 1 is a partially cross-sectioned view illustrating the device for controlling the penetration depth of a needle according to the present invention, said device being generally indicated by the reference number 1, this figure further showing a syringe 4 to which said device 1 is coupled.

The device 1, specifically designed for application to said intradermal injection syringe 4, comprises a skin contacting element specifically designed for contacting the skin 8 of a patient, said skin contacting element holding therein a needle 3.

Said skin contacting element 8 comprises a cylindric portion, defining an outer cylindric body 5, and ending with a tapering or conic portion 2.

The tapering portion 2 encompasses the tip of the needle 3 and has, at said needle 3 tip, a surface 20.

Preferably, said surface 20 has a

substantially spheric cap configuration, and its concavity is facing the tip of the needle 3.

Moreover, said needle 3 tip projects, for a short length, from the surface 20.

Inside the outer cylindric body 5 an inner cylindric body 6 is provided, which is substantially coaxial to said outer cylindric body 5.

The inner cylindric body 6 supports the needle 3 and is provided with a circular rim or edge 9, opposite to the end therefrom projects the tip of the needle 3, and which is arranged inside the outer cylindric body 5.

Moreover, said tapering portion 2 is provided with a plurality of throughgoing microholes 7 passing through the surface 20.

The device 1 for controlling the penetration depth of a needle according to the present invention operates a follows.

More specifically, the device 1 is applied to contact the skin 8 of the patient, i.e. such that the edge of the surface 20 would be brought into contact with the patient skin 8.

In this position, the device 1 is slightly pressed to cause the skin 8 to be slightly deformed in order to allow the needle 3 to enter the skin for a set length.

Then, the substance held in the syringe 4 will be injected into the patient skin 8, according to a per se known manner, by pressing on the syringe 4 plunger.

Upon ending the intradermal injection, the device 1 will be moved away from the patient skin 8

thereby allowing the skin to resiliently recover to its starting configuration, to favor the injected substance to be easily absorbed by the derma and, then, in the blood system.

In this connection it should be pointed out that the provision of the above mentioned microholes 7, or any other throughgoing holes, through the tapering portion 2 of the device 1 will prevent any suction cup effect due to a pressure difference between the inside of the tapering portion 2 and the outer atmospheric pressure from occurring.

In fact, said microholes 7, or any other types of throughgoing holes to be formed through the tapering portion 2, will allow air to outflow as the intradermal injection is carried out.

Thus, the syringe 4 will be prevented from adhering to the patient skin with its end tapering portion 2, which adhesion would compel the operator to forcibly detach the syringe from the skin of the patient.

The mentioned suction cup effect would be particularly dangerous in those cases in which the treatment would provide a plurality of subsequent injections.

Moreover, since the edge or rim of the surface 20 is slightly pressed against the skin 8 of the patient, this would allow the area encompassing the needle 3 puncture to be sensitized thereby the slight pain feeling affecting the patient during the intradermal injection will be further reduced, while assuring a greater pain release to the patient, mainly in the case of repeated injections.

CLAIMS

1. A device for controlling the penetration depth of a needle, for application to an injection syringe, characterized in that said device comprises a skin contacting element, said skin contacting element including a surface encompassing, at least partially, the tip of said needle, and in that said skin contacting element is operatively associated with coupling means for connection with said syringe.

2. A device for controlling the penetration depth of a needle, for application to an injection syringe, according to Claim 1, characterized in that said skin contacting element comprises an end tapering potion ending with said surface.

3. A device for controlling the penetration depth of a needle, for application to an injection syringe, according to Claim 1 or 2, characterized in that said surface has a spheric cap configuration and presents the concavity thereof facing the tip of the needle.

4. A device for controlling the penetration depth of a needle, for application to an injection syringe, according to one or more of the preceding claims, characterized in that said tip of said needle projects for a short length from said surface.

5. A device for controlling the penetration depth of a needle, for application to an injection syringe, according to one or more of the preceding claims, characterized in that said tapering portion comprises a plurality of throughgoing microholes passing through said surface.

6. A device for controlling the penetration depth of a needle, for application to an injection syringe, according to one or more of the preceding claims, characterized in that said means for coupling said skin contacting element to said syringe comprise an outer cylindric body ending with said tapering portion and an inner cylindric body, substantially coaxial to said outer cylindric body and supporting said needle.

7. A device for controlling the penetration depth of a needle, for application to an injection syringe, according to Claim 6, characterized in that said inner cylindric body is provided with a circular rim, opposite to the end portion therefrom said tip of said needle projects, wherein said circular rim is arranged inside said outer cylindric body.

WO 99/34850 PCT/IT98/00262

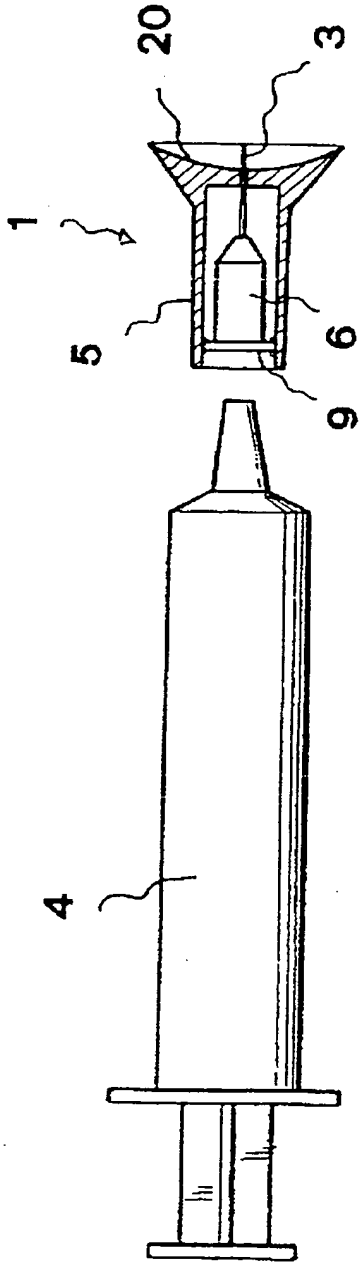

FIG. 1

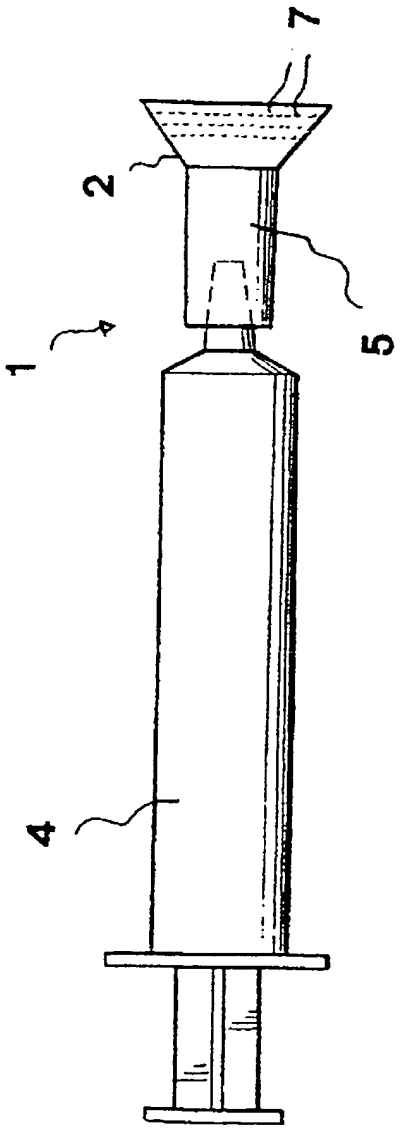

FIG. 2

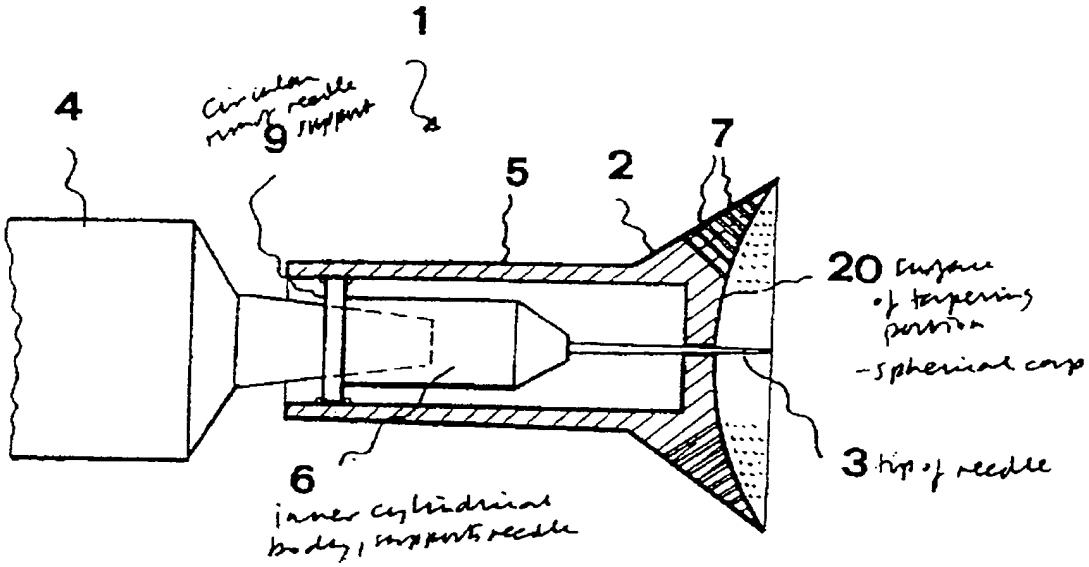

FIG. 3

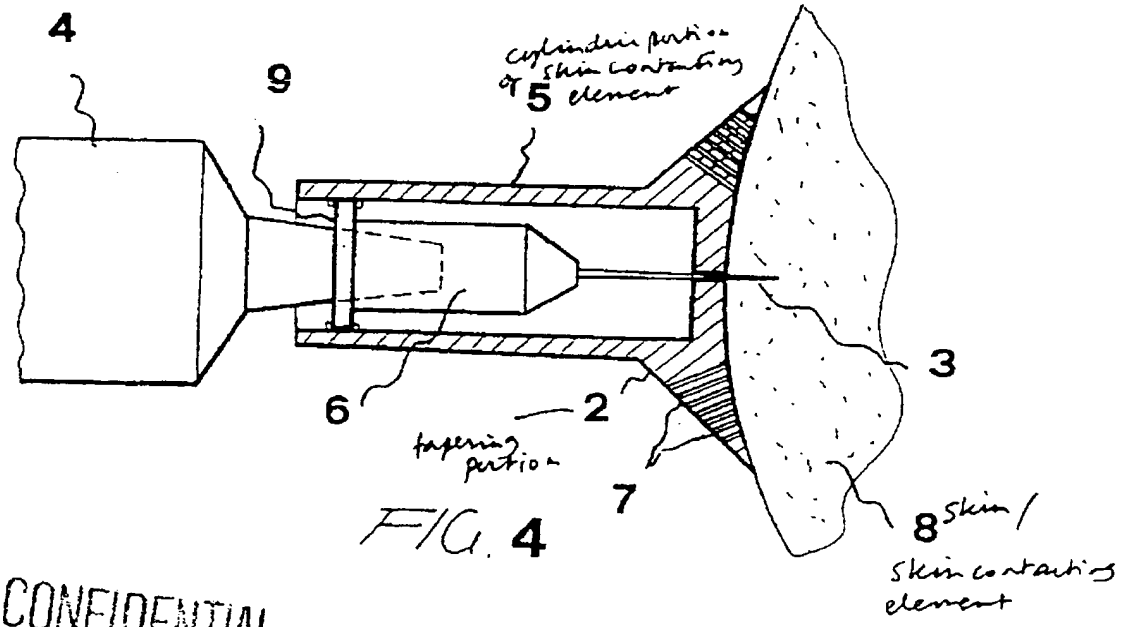

FIG. 4

INTERNATIONAL SEARCH REPORT

Int. ional Application No
PCT/IT 98/00262

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61M5/46

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
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Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

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C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 3 400 715 A (PEDERSON) 10 September 1968 see column 2, line 10 - line 14; claims 1,2; figures 1,3,4	1,3
Y		5
X	WO 95 01198 A (PARK) 12 January 1995 see page 5, line 7 - page 6, line 14; figures 3-7	1,2,4
Y	US 2 876 770 A (WHITE) 10 March 1959 see column 3, line 56 - line 59; figures 1-4	5
A	FR 2 612 401 A (DENANCE) 23 September 1988 see abstract; figures	6

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Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 578 014 A (EREZ URI ET AL) 26 November 1996 see column 4, line 52 - line 61; figure 4A	7

1

INTERNATIONAL SEARCH REPORT

Information on patent family members

Int. ional Application No
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Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 3400715 A	10-09-1968	NONE	
WO 9501198 A	12-01-1995	KR 9700475 Y AU 7085594 A	24-01-1997 24-01-1995
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LA MICROTERAPIA

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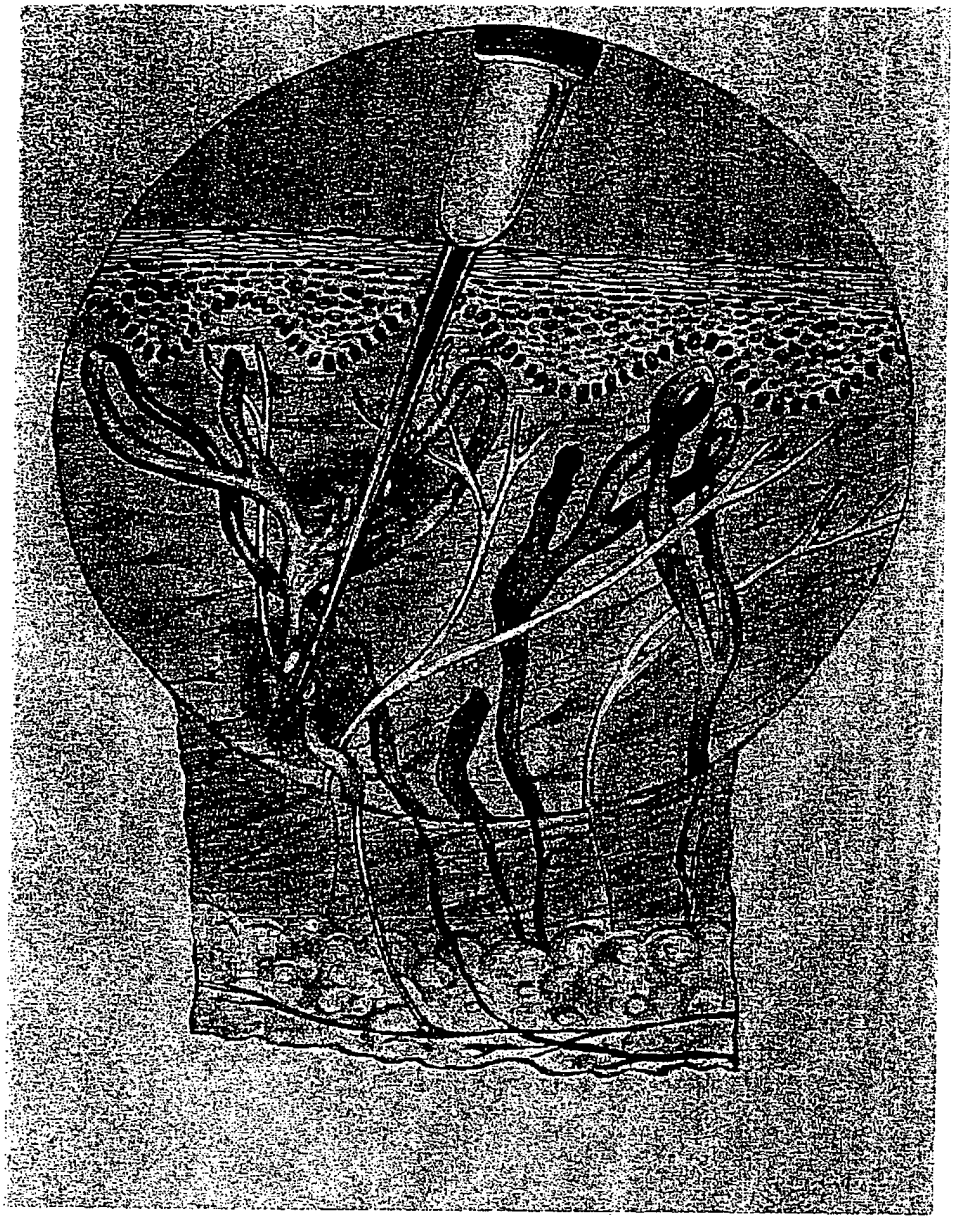
Dott. Antonino Di Pietro



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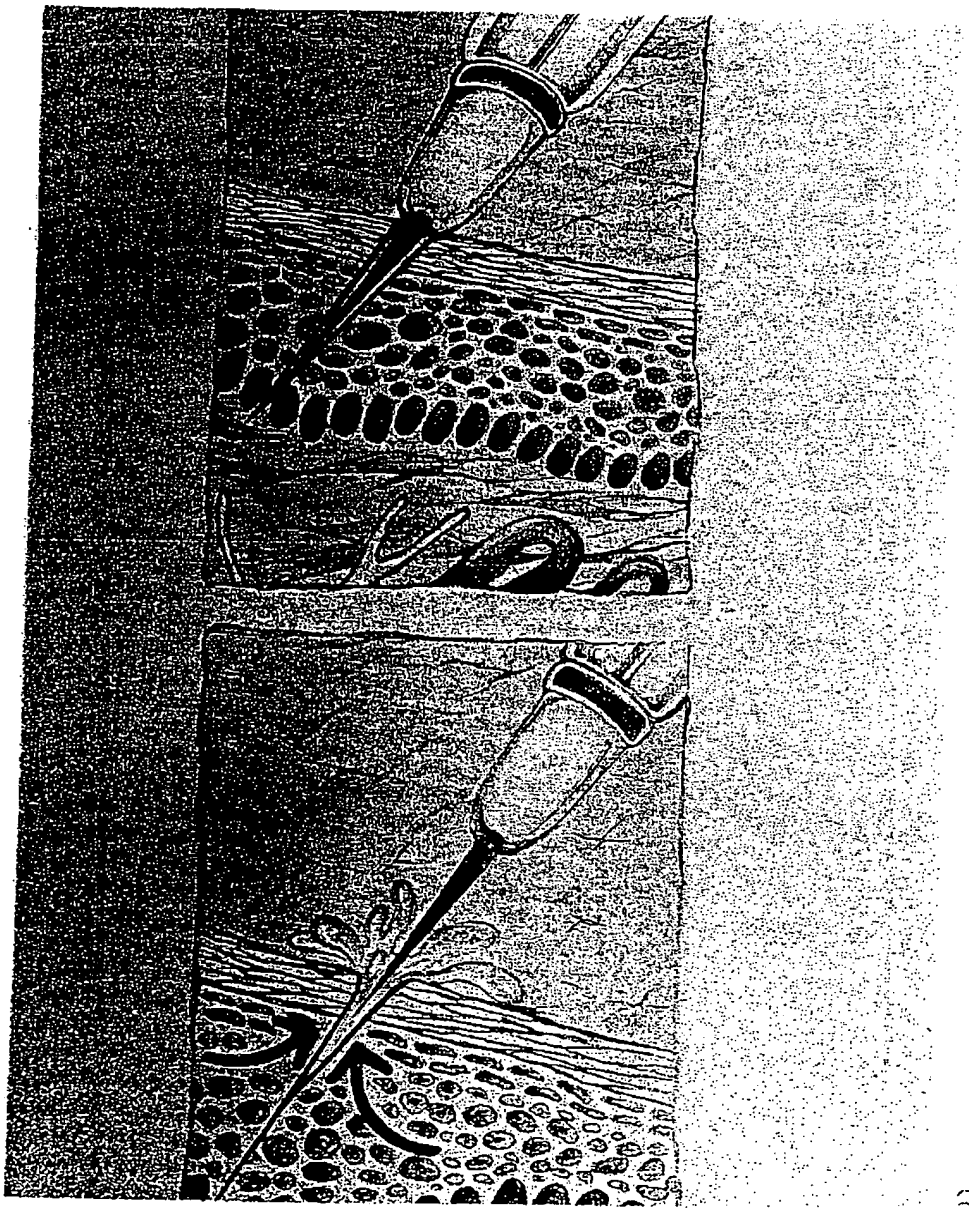
In particolare si è osservato che con la **mesoterapia** la penetrazione dell'ago nel derma medio profondo **causa**: [Fig. 1]

- la **rottura delle arteriole** e conseguente formazione di stravasi ecchimotici.
- La **rottura delle venule**: questa crea un effetto "idrovora" che porta ad un più rapido riassorbimento del farmaco iniettato e quindi ad una **minore compliance** della sua azione.
- Un **insulto del derma** medio profondo che é responsabile di processi infiammatori e fenomeni di riparazione tissutale, i quali possono reliquare in **microsclerosi cicatriziali**.
  Questo evento può essere trascurabile nel caso di una iniezione isolata, ma deve essere valutato nelle normali terapie mesoterapiche nelle quali le iniezioni vengono ripetutamente effettuate in zone circoscritte e per lunghi periodi.
- **Danni ai vasi cutanei** e la possibile formazione di microsclerosi cicatriziali che possono compromettere o **far peggiorare** nel tempo la **funzionalità del microcircolo**, il quale risulta già sofferente nel processo cellulitico.
- La recisione di strutture nervose dermiche, responsabile della **sensazione dolorifica** puntoria. Il dolore, talvolta piuttosto intenso é spesso un deterrente alla prosecuzione della mesoterapia.

La risposta a queste problematiche può essere offerta dalla **MICROTERAPIA**.
La caratteristica più importante di questa nuova metodica é la **superficialità d'iniezione**. Si ritiene che sia sufficiente superare lo strato corneo ed utilizzare lo spazio compreso tra l'epidermide e le prime porzioni
del derma papillare (e non oltre) per introdurre le sostanze farmacologiche desiderate.

Da questa sede il farmaco può raggiungere le zone patologiche più profonde senza che vengano compiuti inutili traumi.

Per raggiungere questo scopo non é sufficiente utilizzare un ago di piccola lunghezza. [FIG 2]
Infatti, pungendo una superficie piana-elastica (come quella cutanea), il foro e il tragitto conico creati con l'introduzione dell'ago si richiuderebbero immediatamente spingendo fuori la maggior parte del liquido e trattenendone solo una esigua quantità.
[FIG 3]



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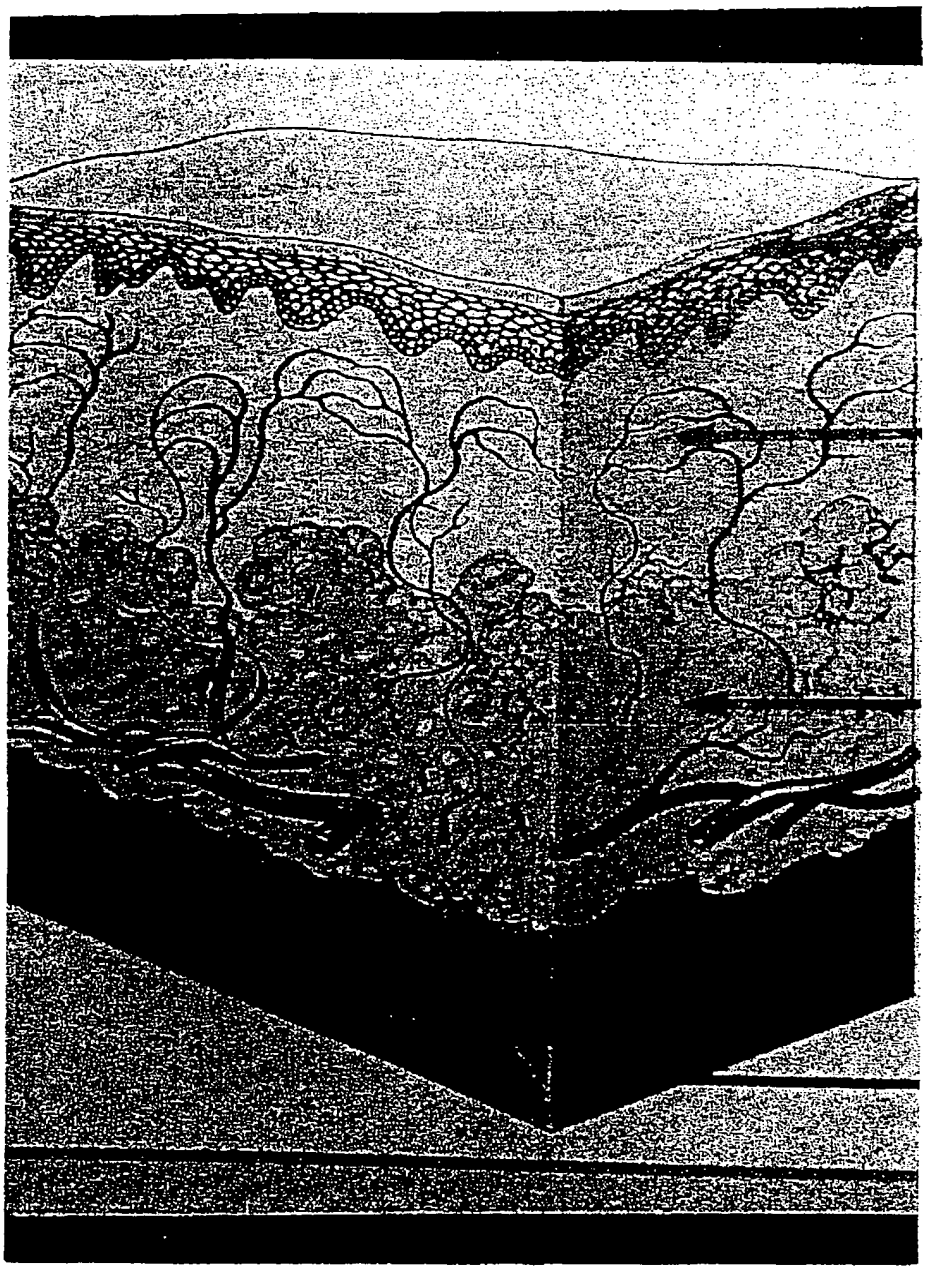
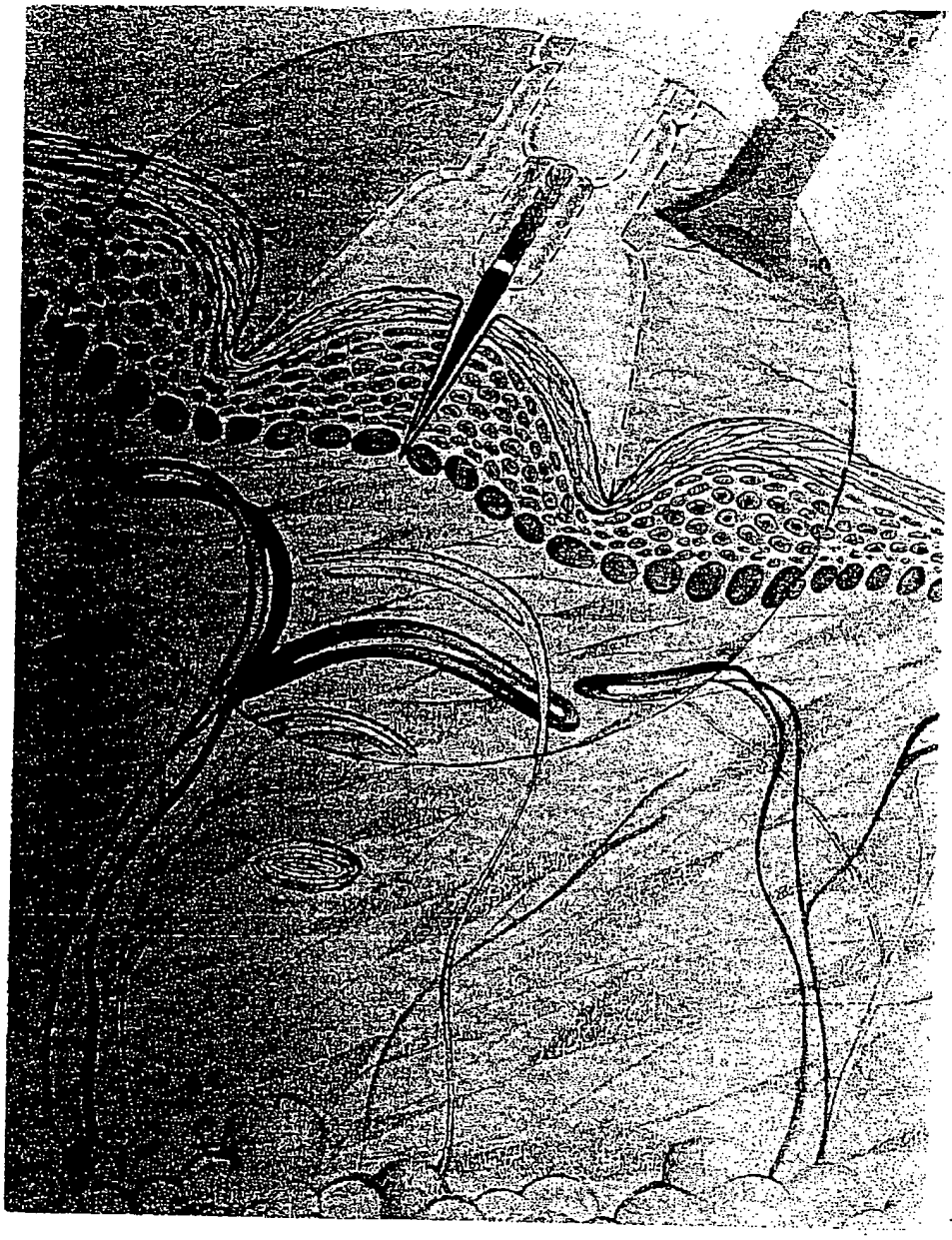
3

La MICROTERAPIA, invece, si basa sull'utilizzo di un dipositivo monouso denominato **S.I.T.®**
(Skin Injection Therapy), con il quale é possibile utilizzare la via transepidermica-papillare con il massimo dell'efficacia.

Il **S.I.T.®**, che é collegato ad una normale siringa, consta di una parte concava rigida dal cui centro fuoriesce un microago.
[fig 4]





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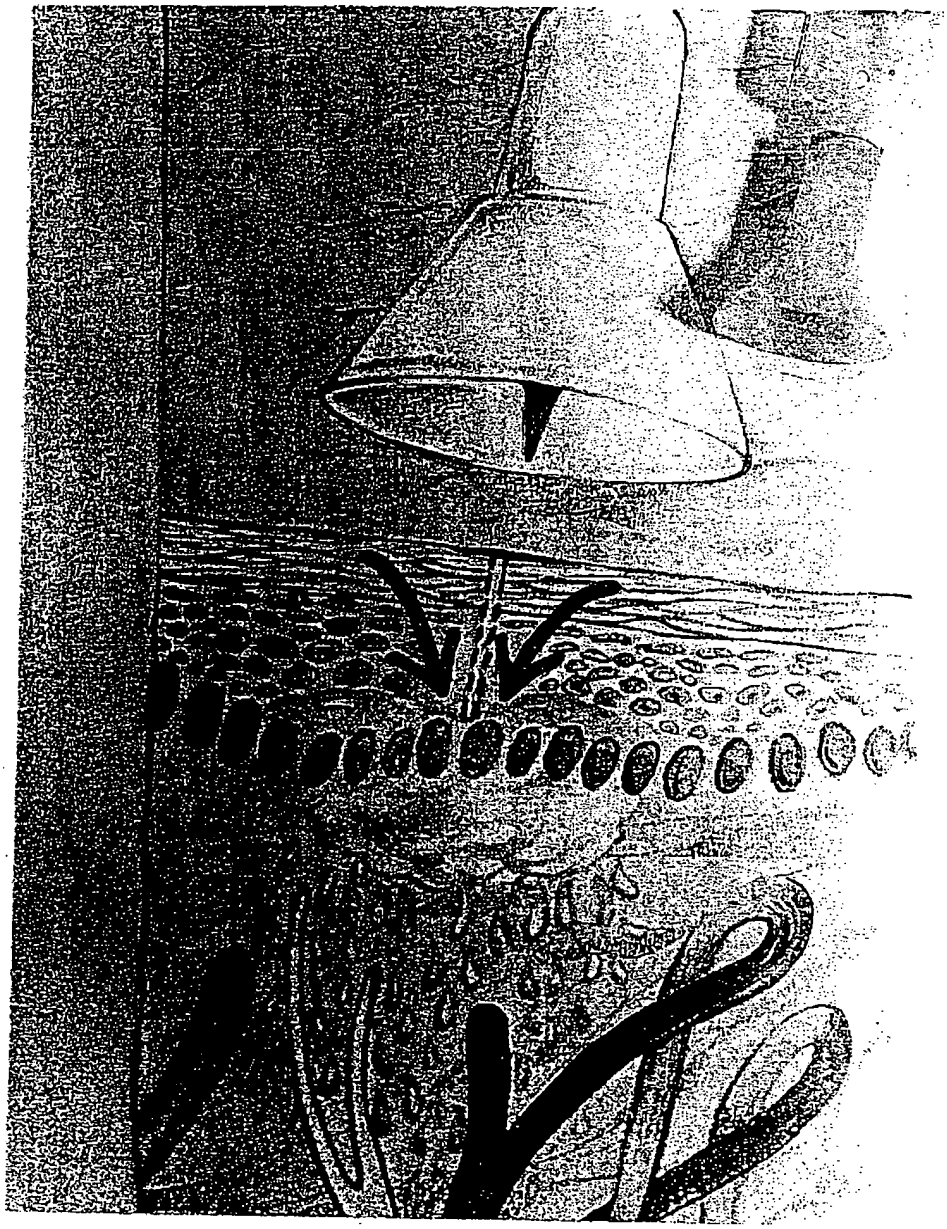
Con la **microterapia** é possibile quindi introdurre farmaci attraverso la cute con i seguenti vantaggi:

- Non si provoca rottura delle arteriole dermiche e non si formano ecchimosi.
- Non si causa rottura delle venule dermiche, pertanto il farmaco iniettato resta in sede più a lungo (azione long-acting).
- Si evitano traumi nel derma medio-profondo responsabili di processi infiammatori e di riparazione tissutali che possono generare microscierosi cicatriziali.
- Non si compromette la funzionalità del microcircolo.
- Non vengono interessate terminazioni nervose di medio-grosso calibro pertanto non si avverte il vivo dolore puntorio. Inoltre la pressione circolare esercitata dal bordo del **S.I.T.®** compie un effetto locale anestetico (effetto pizzicotto) che annulla quasi completamente ogni sensazione dolorifica.

Appoggiando il S.I.T.® sulla cute ed esercitando una leggera pressione, la pelle aderirà elasticamente lungo la concavità e contemporaneamente il microago penetrerà all'interno dell'epidermide e del derma papillare, permettendo l'iniezione del farmaco. [FIG 5]

Successivamente, sollevando il dispositivo dalla superficie cutanea, la calotta cupoliforme di cute, prima formatasi si appianerà. Il foro centrale, creato dall'ago, dapprima tenuto dilatato dalla stessa curvatura elastica cutanea, si richiuderà immediatamente trattenendo il liquido iniettato. Lo stesso liquido verrà spinto più in profondità nel derma dalla forza elastica di appiattimento del tessuto, senza alcun trauma per le strutture dermiche profonde.

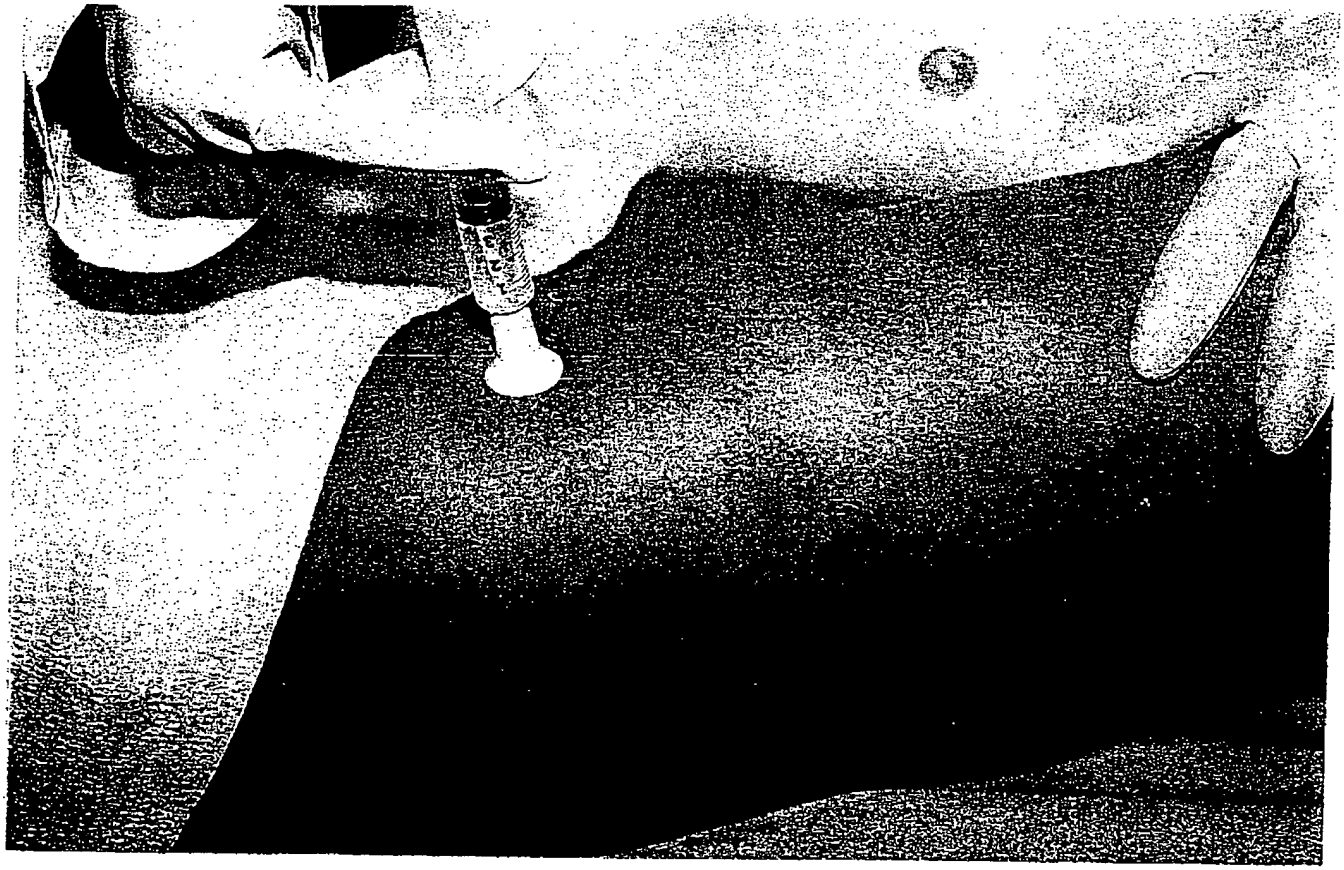
[FIG 6]



Le prospettive

La **microterapia** si propone soprattutto come nuovo metodo per il trattamento della **cellulite** ma, per la sua superficialità di azione, potrebbe rappresentare una metodica utile per stimolare i cheratinociti epidermici, i quali sotto l'azione di farmaci o molecole adatte, sarebbero indotti a produrre e rilasciare citochine.

La stimolazione di citochine specifiche, stimolanti la riproduzione di popolazioni cellulari cutanee ed inibenti la loro lisi potrebbe ad esempio rappresentare un passo avanti nel controllo dell'**invecchiamento cutaneo**.



MICROTERAPIA CON "S.I.T."

Le finalità

La microterapia è stata ideata per poter introdurre farmaci nello spessore della cute in modo efficace e poco traumatico, in particolare evitando gli esiti della Mesoterapia classica:

- La rottura dei vasi capillari
- La lesione delle fibre propriocettive dolorifiche dermiche
- La formazione di microsclerosi cicatriziali

La prima applicazione di questa nuova metodica è stata a lungo sperimentata per il trattamento per la cellulite con l'obbiettivo terapeutico di promuovere il riassorbimento dell'edema che si associa alla cellulite e che comprimendo i tessuti localmente causa deficit di circolo e perpetua il processo cellulitico.
Utilizzando la tecnica della Microterapia, si iniettano nel derma papillare microdosi (dose imbibente) di una soluzione salina ipertonica che per osmosi richiama i liquidi edematosi ristagnanti in superfice, verso il derma medio dove i vasi sanguigni e linfatici non traumatizzati possono svolgere un drenaggio fisiologico dell'edema.
L'eliminazione di quest'ultimo riduce la compressione e riattiva il microcircolo adipocitario, permette la ripresa del metabolismo lipidico e della lipolisi endogena con un globale miglioramento del quadro iniziale.

La tecnica

Prendendo come esempio il trattamento di un arto inferiore, si eseguiranno le microiniezioni distanziate di circa 2 cm. una dall'altra, formando delle linee verticali che percorrono l'arto in tutta la sua lunghezza (dalla radice alla coscia sino alla caviglia).
In questo modo si avranno delle linee parallele, distanziate tra loro di circa 2 cm. che interesseranno tutta la circonferenza dell'arto, sino a formare una rete ideale che lo comprenda interamente.
La siringa da 5 ml. è sufficiente per circa 100 iniezioni, quindi per coprire circa un 50% di un arto inferiore.

1. Inserire il Microiniettore S.I.T. su di una normale siringa monouso di capacità non superiore a 5 ml. per poter meglio controllare le minime quantità da iniettare, all'inizio si consiglia di utilizzare anche siringhe di capacità inferiore per un migliore controllo ed abituarsi alle microdosi da iniettare.
2. Stringere la siringa tra indice e medio (come una sigaretta) ed appoggiare il SIT sulla cute.
3. Accertarsi che la circonferenza del SIT aderisca bene e sia il più possibile perpendicolare alla cute.
4. Tenendo ben salda la siringa, premere il SIT contro il piano cutaneo da trattare, esercitando una pressione di media forza.
5. Compiere con il pollice una leggerissima e brevissima pressione sullo stantuffo della siringa.
6. Evitare spinte eccessive sullo stantuffo perché si formerebbero dei ponfi (dannosi perché finirebbero con il comprimere e danneggiare il delicato tessuto papillare sottostante) ed inoltre si avrebbe un inutile spreco di farmaco. La cute sotto la pressione del SIT è tesa, bioccata dalla calotta del Microiniettore, il foro dell'ago si dilata leggermente e spingendo troppo forte sullo stantuffo della siringa, il tessuto sottostante fa resistenza ed il farmaco fuoriesce.
7. Se la pressione è stata corretta, sollevando il SIT, sulla cute dovrà restare solo una piccola goccia di liquido, esito dello scarico di tensione del pistone in gomma della siringa.
8. Asciugare con un batuffolo di cotone.

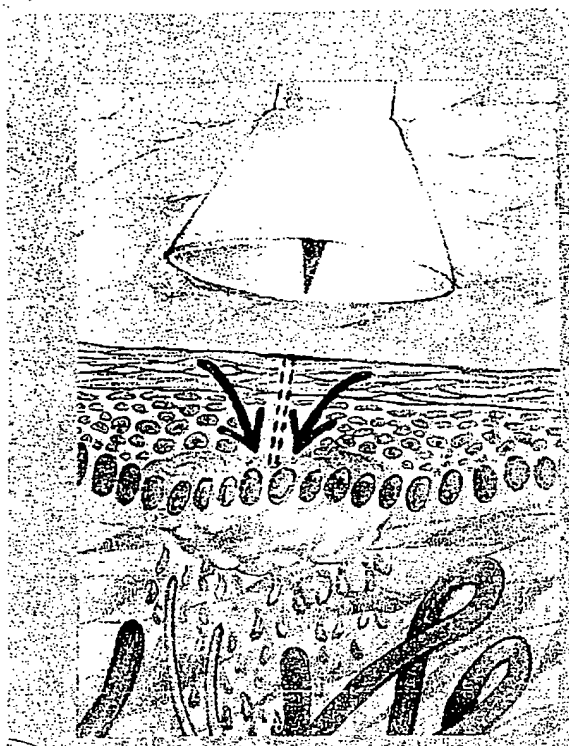


Fig. 3

foro di iniezione si rinchiude impedendo il riflusso del farmaco iniettato (Fig. 3) al contrario delle iniezioni di Mesoterapia con ago semplice (Fig. 4).

Questa tecnica è stata comprovata sperimentalmente innumerevoli volte la piccola goccia che rimane sulla pelle dopo il rilascio della pressione è dovuta alla tensione del pistone in gomma nera della siringa che si comporta come una camera elastica.

La tecnica della Microterapia superficiale, ottenibile con l'uso del S.I.T. consente di ottenere dal farmaco iniettato la sua massima attività e permette di evitare gli effetti collaterali ed i fattori di rischio della Mesoterapia classica.

1 - rottura di arteriole con susseguenti ematomi

2 - rottura di venule attraverso le quali il farmaco viene riassorbito troppo rapidamente con conseguente diminuzione della sua attività.

3 - lesioni al derma profondo con esiti cicatriziali indesiderati

4 - iniezioni dolorose a causa di lacerazioni delle terminazioni nervose superficiali.

La Microterapia si propone come nuovo metodo di trattamento mesoterapico, esente da rischi e fenomeni collaterali indesiderati, utile nel trattamento della cellulite ed in tutte le pratiche mediche associate alla Mesoterapia.

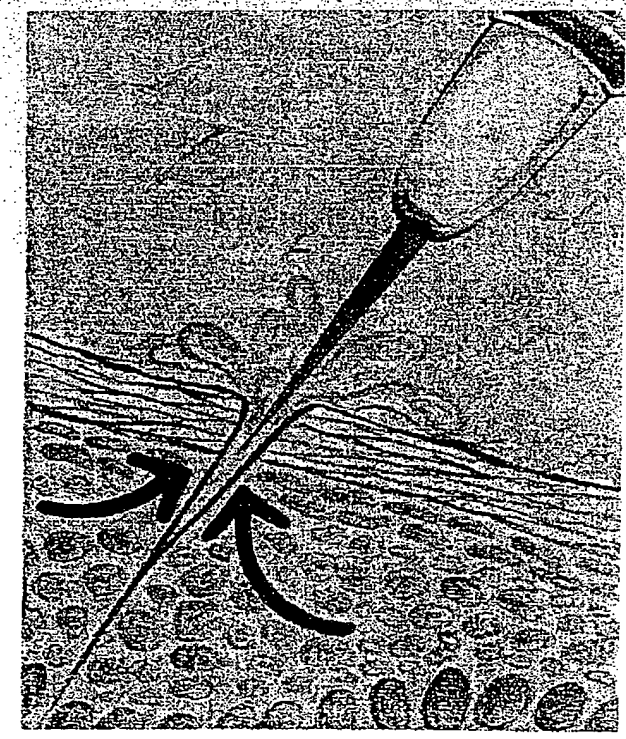


Fig. 4

S.I.T.* (Skin injection Therapy)
Iniettore monouso per Microterapia

La Microterapia, modifica evolutiva della Mesoterapia, è una recente tecnica iniettiva per la somministrazione di farmaci per via intradermica superficiale e si somma alle classiche vie di somministrazione iniettiva intramuscolare, endovenosa e sottocutanea.

Fig 1

Mentre per la pratica della Mesoterapia si utilizzano aghi (lunghezza 4 mm.) che portano il farmaco sino al livello del derma profondo, per la Microterapia si utilizza il S.I.T. (v. Fig. 1), uno strumento monouso a forma di imbuto rovesciato che al centro porta uno speciale sottilissimo ago 32G x 2 mm (0.27 x 2 mm) grazie al quale il farmaco viene somministrato a livello del derma superficiale (strato papillare), subito al disotto dello strato corneo della pelle.

Il S.I.T. illustrato in Fig. 1, va innestato su una normale siringa monouso preriempita, la parte a campana va posata sulla pelle e va mantenuta premuta durante l'iniezione (vedi Fig. 2).

La forma del S.I.T. obbliga la pelle a tendersi ed a curvarsi, in modo da rendere l'iniezione del farmaco indolore ed assolutamente non traumatica.

La pelle ritorna alla sua tensione normale al termine della iniezione quando si rilascia la pressione ed il

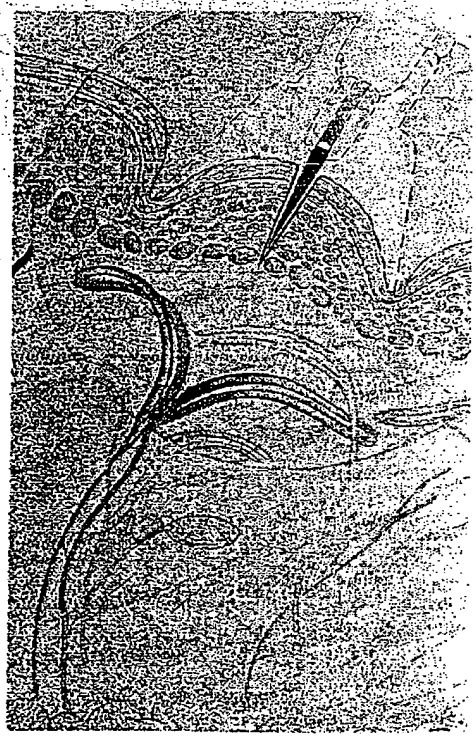


Fig. 2

* S.I.T.: marchio e brev

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